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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/005,318 | 01/09/1998 | MICH B. HEIN | 310098401C1 | 2353 |
| 826 | 7590 | 11/01/2005 | EXAMINER | |
| ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000 | | | ROMEO, DAVID S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 09/005,318 | Applicant(s) HEIN ET AL. | |
| | Examiner David S. Romeo | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-47, 52, 54-69 and 73-80 is/are pending in the application.
- 4a) Of the above claim(s) 75 and 78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-47, 52, 54-69, 73, 74, 76, 77, 79 and 80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 42-47, 52, 54-69 and 73-80 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 07/26/2005 has been entered. Claims 42-47, 52, 54-69, 73-80 are pending. Applicants' election of the species of targeting molecule comprising a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8 covalently linked via a peptide bond to an antigen combining site is acknowledged. Claims 44, 46-49, 51, 53, 66, 75, 78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed 12/18/2002.

Maintained Formal Matters, Objections, and/or Rejections:***Double Patenting***

Claims 42-47, 52, 54-69, 73-80 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 08/782,481. It is acknowledged that Applicants will file a terminal disclaimer when the claims are otherwise allowable.

Claims 42-47, 52, 54-69, 73-80 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 7 of U.S. Patent No. 6440419. It is acknowledged that Applicants will file a terminal disclaimer when the claims are otherwise allowable.

Claims 42-47, 52, 54-69, 73-80 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending

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Application No. 10/062467. It is acknowledged that Applicants will file a terminal disclaimer when the claims are otherwise allowable.

Claim Rejections - 35 USC § 112

Claims 73, 74, 76, 77 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that claims 73, 74, 76, 77 have been amended to recite specific SEQ ID NOs:, and that this rejection has been overcome. Applicant's arguments have been fully considered but they are not persuasive. Claims 73, 74, 76, 77 have not been amended to recite specific SEQ ID NOs:. Claims 73, 74, 76, 77 are directed to or encompass a targeting molecule that contains (a), forms (b), comprises at least domain 2 of a J chain, and does not contain any of CH1 α , CH2 α , CH3 α , and CL. The only working examples in the present specification (Example 3) show the targeting of various biological agents linked to "TM." What constitutes "TM" in these examples cannot be ascertained. The evidence cited by the examiner shows that although the presence of the J chain in IgA or IgM polymers is needed in order to obtain SC binding, the J chain by itself does not constitute an SC-binding site. Accordingly, a description of a J chain or J chain portion or forms (a) and contains (b) is not a description of a targeting molecule that binds an epithelial basolateral factor and is not a description of a J chain portion that is characterized in having the ability to bind to an epithelial basolateral factor.

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Claims 73, 74, 76, 77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a targeting molecule comprising a J chain and the CH2 and CH3 domains of IgA or IgM, does not reasonably provide enablement for a targeting molecule that contains (a), forms (b), comprises at least domain 2 of a J chain, and does not contain any of CH1 α , CH2 α , CH3 α , and CL. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants argue that claims 73, 74, 76, 77 have been amended to recite specific SEQ ID NOs:, and that this rejection has been overcome. Applicant's arguments have been fully considered but they are not persuasive. Claims 73, 74, 76, 77 have not been amended to recite specific SEQ ID NOs:. Claims 73, 74, 76, 77 are directed to or encompass a targeting molecule that contains (a), forms (b), comprises at least domain 2 of a J chain, and does not contain any of CH1 α , CH2 α , CH3 α , and CL. The only working examples in the present specification (Example 3) show the targeting of various biological agents linked to "TM." What constitutes "TM" in these examples cannot be ascertained. The evidence cited by the examiner shows that although the presence of the J chain in IgA or IgM polymers is needed in order to obtain SC binding, the J chain by itself does not constitute an SC-binding site. In the absence of a minimal structure required to generate an SC-binding site a skilled practitioner would have to resort to a substantial amount of undue experimentation before they could even begin to rationally design a functional TM having other than a J chain and the CH2 and CH3 domains of IgA or IgM.

Claim Rejections - 35 USC § 102

Claims 73, 74, 76, 77 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wallner (WO 92/16622).

Applicants argue that Wallner does not teach a targeting molecule comprising SEQ ID NO: 114, 115, 116, 117, 118, or 119 or the amino acid sequence encoded by nucleotides 1-414 of SEQ ID NO: 7 or the amino acid sequence encoded by nucleotides 1-213 of SEQ ID NO: 8. Applicant's arguments have been fully considered but they are not persuasive. Claims 73, 74, 76, 77 are not limited to a targeting molecule comprising SEQ ID NO: 114, 115, 116, 117, 118, or 119 or the amino acid sequence encoded by nucleotides 1-414 of SEQ ID NO: 7 or the amino acid sequence encoded by nucleotides 1-213 of SEQ ID NO: 8.

Claims 73, 74, 76, 77 are rejected under 35 U.S.C. 102(e) as being anticipated by Capra (U. S. Patent No. 6,063,905).

Applicants argue that claims 73, 74, 76, 77 depend from claim 42 and that Capra does not teach a targeting molecule comprising SEQ ID NO: 114, 115, 116, 117, 118, or 119 or the amino acid sequence encoded by nucleotides 1-414 of SEQ ID NO: 7 or the amino acid sequence encoded by nucleotides 1-213 of SEQ ID NO: 8. Applicant's arguments have been fully considered but they are not persuasive. Claims 73, 74, 76, 77 do not depend from claim 42 and are not limited to a targeting molecule comprising SEQ ID NO: 114, 115, 116, 117, 118, or 119 or the amino acid sequence encoded by nucleotides 1-414 of SEQ ID NO: 7 or the amino acid sequence encoded by nucleotides 1-213 of SEQ ID NO: 8.

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Claim Rejections - 35 USC § 103

Claims 73, 74, 76, 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Max (J Exp Med. 1985 Apr 1;161(4):832-49) and Janknecht (Gene. 1992 Nov 16;121(2):321-4).

Applicants argue that claims 73, 74, 76, 77 depend from claim 42 and that the cited references alone or in combination do not teach a targeting molecule comprising SEQ ID NO: 114, 115, 116, 117, 118, or 119 or the amino acid sequence encoded by nucleotides 1-414 of SEQ ID NO: 7 or the amino acid sequence encoded by nucleotides 1-213 of SEQ ID NO: 8. Applicant's arguments have been fully considered but they are not persuasive. Claims 73, 74, 76, 77 do not depend from claim 42 and are not limited to a targeting molecule comprising SEQ ID NO: 114, 115, 116, 117, 118, or 119 or the amino acid sequence encoded by nucleotides 1-414 of SEQ ID NO: 7 or the amino acid sequence encoded by nucleotides 1-213 of SEQ ID NO: 8.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
OCTOBER 20, 2005